Innovative Administration Systems for Vaccines AGENDA

Thursday, December 18, 2003

8:30 A.M. – 10:00 A.M. Introduction and Overview Plaza I/II

Chair: Jerome Donlon, M.D., Ph.D.

Senior Science Advisor

Department of Health and Human Services

Washington, DC, USA

8:30 A.M. – 8:45 A.M. **Welcome**

D.A. Henderson, M.D. [invited] Principal Science Advisor Office of the Secretary

Department of Health and Human Services

Washington, DC, USA

8:45 A.M. – 9:20 A.M. *Keynote Address*:

A Needle-Free Vision

Myron Levine, M.D., D.T.P.H.

Professor and Director, Center for Vaccine Development

University of Maryland School of Medicine

Baltimore, Maryland, USA

9:20 A.M. – 9:40 A.M. **Mainstreaming New Immunization Technologies**

John Lloyd

Associate Director, Children's Vaccine Program

Program for Appropriate Technology in Health (PATH)

Ferney-Voltaire, France

9:40 A.M. – 10:00 A.M. Grand Challenges in Global Health: Vaccine Priorities

Carol Dahl, Ph.D. Associate Director

Global Health Technologies

Bill and Melinda Gates Foundation

Seattle, Washington, USA

10:00 A.M. – 10:15 A.M. Break Outside Regency Room

10:15 A.M. – 12:00 NOON Transdermal Administration Plaza I/II

10:15 A.M. – 10:20 A.M. Chair: M. Louise Pitt, Ph.D.

Chief, Department, of Aerobiology & Product Evaluation

U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)

Frederick, Maryland, USA

0310025F.doc V

10:20 A.M. – 10:45 A.M. Cutaneous or Mucosal Delivery of Anthrax rPA

Provides Protection against Inhalational Anthrax

John A. Mikszta

Team Leader, Immunology

BD Technologies

Research Triangle Park, North Carolina, USA

10:45 A.M. – 11:10 A.M. **Epid**e

Epidermal Powder Immunization

Dexiang Chen, Ph.D.

Director, Vaccine Research

PowderJect Vaccines

Middleton, Wisconsin, USA

11:10 A.M. – 11:35 A.M.

Completely Stable Liquid Vaccines and Disposable

Safety Injectors

Bruce J. Roser, Ph.D.

Chief Scientist

Cambridge Biostability Ltd. Cambridge, United Kingdom

11:35 A.M. – 12:00 P.M.

Transcutaneous Immunization

Gregory Glenn, M.D.

Senior Vice President and Science Director

IOMAI, Inc.

Gaithersburg, Maryland, USA

12:00 P.M. - 1:30 P.M.

Lunch

On Own

1:30 P.M. - 3:25 P.M.

Jet Injection of Vaccines

Plaza I/II

(Part I)

Chair: Bruce G. Weniger, M.D., M.P.H. Assistant Chief for Vaccine Development

Immunization Safety Branch National Immunization Program

Centers for Disease Control and Prevention

Atlanta, Georgia, USA

1:30 P.M. – 1:55 P.M.

Overview and Challenges for Mass

Vaccination with Jet Injectors (JIs)

Bruce G. Weniger, M.D., M.P.H.

Assistant Chief for Vaccine Development

Immunization Safety Branch National Immunization Program

Centers for Disease Control and Prevention

Atlanta, Georgia, USA

0310025F.doc VI

1:55 P.M. - 2:15 P.M.Solving the Problems of Mass Vaccination with Needle-Free Technology Michael Mathews Vice President, Felton International, Inc. Lenexa, Kansas, USA 2:15 P.M. - 2:40 P.M.Safety Evaluation of Re-designed Multi-**Use-Nozzle Jet Injectors (MUNJIs) for Developing Countries** Martin Friede, Ph.D. Technical Officer, Initiative for Vaccine Research, Immunization Vaccines and Biologicals World Health Organization Geneva, Switzerland 2:40 P.M. - 3:05 P.M.Experience and Lessons from a Market-Pioneering, Disposable-Cartridge Jet Injector (DCJI): "The Future of Injection Therapy in Your Hands Today" Kurt Lynam National Sales Manager, Bioject, Inc. Portland, Oregon, USA 3:05 P.M. - 3:25 P.M.**LectraJet ® - Needle-Free Injection System for Routine Immunization and Mass Immunization Campaigns** Linda D'Antonio Vice President, D'Antonio Consultants International (DCI), Inc. East Syracuse, New York, USA 3:25 P.M. - 4:25 P.M.Exhibition Time and Break Regency Room 4:25 P.M. - 5:45 P.M. Plaza I/II **Jet Injection of Vaccines** (Part II) Chair: Bruce G. Weniger, M.D., M.P.H. Assistant Chief for Vaccine Development Immunization Safety Branch **National Immunization Program** Centers for Disease Control and Prevention Atlanta, Georgia, USA 4:25 P.M. - 4:50 P.M.PATH's Experience from Jet Injector R&D and Field Assessment in Developing **Countries** Darin Lee Zehrung Technical Officer Program for Appropriate Technology in Health (PATH) Seattle, Washington, USA

0310025F.doc Vii

4:50 P.M. - 5:10 P.M.

Roadmap Toward an International Standard for Prefillable, Disposable Jet Injection Cartridges for Both Routine and High-Speed Vaccination in Developing Countries

Martin Friede, Ph.D.

Technical Officer, Initiative for Vaccine Research

Immunization Vaccines and Biologicals

World Health Organization

Geneva, Switzerland

5:10 P.M. − 5:45 P.M.

Panel Discussion: FDA Regulation of Combination Products

All Speakers on Jet Injection of Vaccines (Part I and II)

Introduction: Mark Kramer Director, Office of Combination Products U.S. Food and Drug Administration Rockville, Maryland, USA

0310025F.doc VIII

Friday, December 19, 2003

8:30 A.M. – 3:00 P.M. Promises and Challenges for Mucosal

Delivery Systems

8:30 A.M. – 8:40 A.M. Co-Chairs:

David Klein, Ph.D.

Respiratory Diseases Branch Division of Microbiology and Infectious Diseases

NIAID/NIH

Rockville, Maryland, USA

Dennis Kopecko, Ph.D.

Division of Bacterial Products

Office of Vaccine Research and Review

CBER/FDA

Rockville, Maryland, USA

8:40 A.M. – 9:40 A.M. Mucosal Delivery Devices

Plaza I/II

8:40 A.M. – 9:00 A.M. Flumist Delivery System – The First Nasal Vaccine in

the U.S.

James Young, Ph.D. President, MedImmune Gaithersburg, Maryland, USA

9:00 A.M. – 9:20 A.M. The OptiNose Bi-directional Nasal Delivery Devices for

Vaccines

Per G. Djupesland, M.D., Ph.D.

Head of R & D and Chairman of the Board

OptiNose AS Oslo, Norway

9:20 A.M. – 9:40 A.M. **Vibrating Mesh Technology for Delivering**

Measles Vaccine

Mark Papania, M.D., M.P.H.

Team Leader, Measles, Rubella, Mumps

Elimination Team

Centers for Disease Control and Prevention

Atlanta, Georgia

Mucosal Vectors

Plaza I/II

9:40 A.M. – 10:00 A.M. Live Bacterial Vectors

9:40 A.M. - 11:55 A.M.

Carol Tacket, M.D.

Chief, Adult Clinical Studies Section, Center for Vaccine Development

University of Maryland Baltimore, Maryland, USA

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10:00 A.M. – 10:20 A.M. Targeted Delivery of Mucosal Vaccines

David Lo, M.D., Ph.D.

Vice President of Integrative Biology

Digital Gene Technologies La Jolla, California, USA

10:20 A.M. – 10:35 A.M. Break

Outside Regency Room

10:35 A.M. – 10:55 A.M. Mucosal Immunization against Plague and Anthrax

Using Microparticles

James E. Eyles, Ph.D.

Team Leader, Vaccine Delivery

Defence Science and Technology Laboratory

Porton Down

Salisbury, Wiltshire, United Kingdom

10:55 A.M. – 11:15 A.M. **Bacterial Ghosts as Carrier and Targeting**

Systems for Mucosal Antigen Delivery

Werner Lubitz, M.D.

Institute of Microbiology and Genetics,

University of Vienna Vienna, Austria

11:15 A.M. – 11:35 A.M. **VEE Replicon Vaccines in Development**

Jonathan Smith, Ph.D.

AlphaVAX, Inc.

Research Triangle Park, North Carolina, USA

11:35 A.M. – 11:55 A.M. **Delivery of Plant-Derived Oral Vaccines**

Charles J. Arntzen, Ph.D.

Director, Center for Infectious Diseases

and Vaccinology

Arizona State University Tempe, Arizona, USA

11:55 A.M. – 1:20 P.M. Lunch On Own

1:20 P.M. – 2:20 P.M. Improved Mucosal Delivery Formulations

Plaza I/II

1:20 P.M. – 1:40 P.M. Pluronic F127-Based Systemic and Mucosal Vaccine

Delivery Systems

Claire Coeshott, Ph.D.

RxKinetix, Inc.

Louisville, Colorado, USA

0310025F.doc X

1:40 P.M. – 2:00 P.M. The Use of Novel Biopolymers in Vaccine Encapsulation

Allison Ficht, Ph.D.

Director, Center for Microencapsulation

and Drug Delivery Lab Texas A&M University College Station, Texas, USA

2:00 P.M. – 2:20 P.M. ProteosomeTM Adjuvants for Nasal Vaccines against

Influenza and Plague

Louis F. Fries, M.D.

Vice President of Clinical and Regulatory Affairs

ID Biomedical Corporation Baltimore, Maryland, USA

2:20 P.M. – 2:40 P.M. Microparticles Plaza I/II

2:20 P.M. – 2:40 P.M. Formulation and Delivery Characteristics of

Cochleate Vaccines

Raphael Mannino, Ph.D.

Executive Vice President and CEO BioDelivery Sciences International

Newark, New Jersey, USA

2:40 P.M. – 3:00 P.M. **Vectors**

2:40 P.M. – 3:00 P.M. Phage T4 Display for Vaccine Delivery

Mangala Rao, Ph.D.

Walter Reed Army Institute of Research Department of Membrane Biochemistry

Silver Spring, Maryland, USA

3:00 P.M. − 3:30 P.M. Panel Discussion

3:30 P.M. – 4:00 P.M. Summary and Close of Meeting

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